

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1. (Currently amended) A composition comprising a recombinant polynucleotide that encodes a modified Factor VII, said modified Factor VII comprising a proteolytic cleavage site at a location that allows secretion of active Factor VII upon cleavage, said proteolytic cleavage site comprising the amino acid sequence of ~~having the sequence Arg-Lys-Arg-Arg-Lys-Arg (as set forth in SEQ ID NO: 1), wherein said proteolytic cleavage site is and~~ not normally present in Factor VII.
2. (Previously presented) The composition of claim 1, wherein the Factor VII is a functional variant or a functional subsequence of a naturally occurring Factor VII.
- 3.-12. (Canceled)
13. (Previously presented) The composition of claim 1, wherein the proteolytic cleavage site is introduced between amino acids 152 and 153 of Factor VII.
14. (Previously presented) The composition of claim 1, wherein the proteolytic cleavage site is introduced between arginine 152 and isoleucine 153 of Factor VII.
15. (Canceled)
16. (Canceled)
17. (Currently amended) The composition of claim 2, wherein the functional variant has one or more conservative amino acid substitutions of relative to wild type Factor VII.
18. (Original) The composition of claim 2, wherein the functional variant comprises a Factor VII having increased activity relative to wild type Factor VII.

19. (Original) The composition of claim 2, wherein the functional variant comprises a Factor VII having increased stability in vivo relative to wild type Factor VII.
20. (Original) The composition of claim 2, wherein the functional variant comprises a Factor VII having decreased immunogenicity relative to wild type Factor VII.
21. (Previously presented) The composition of claim 1, wherein the Factor VII is mammalian.
22. (Previously presented) The composition of claim 21, wherein the Factor VII is primate, canine, feline, porcine, equine or bovine.
23. (Original) The composition of claim 22, wherein the primate is human.
24. (Previously presented) The composition of claim 1, wherein the recombinant polynucleotide encoding the modified Factor VII is operatively linked to a regulatable or tissue specific expression control element.
25. (Original) The composition of claim 24, wherein the regulatable or tissue specific expression control element comprises a promoter.
26. (Original) The composition of claim 24, wherein the promoter comprises a skeletal muscle actin promoter or a muscle creatine kinase promoter.
27. (Original) The composition of claim 24, wherein the tissue specific expression control element confers expression of the modified blood clotting factor in muscle, liver, kidney or blood vessel endothelium.
28. (Original) The composition of claim 24, wherein the regulatable expression control element comprises elongation factor 1 α promoter.

29. (Currently amended) A composition comprising a vector comprising and a recombinant polynucleotide that encodes a modified Factor VII, said modified Factor VII comprising a proteolytic cleavage site at a location that allows secretion of active Factor VII upon cleavage, said proteolytic cleavage site comprising the amino acid sequence of SEQ ID NO: 1, wherein said proteolytic cleavage site is not normally present in Factor VII the recombinant polynucleotide of claim 1.

30. (Original) The composition of claim 29, wherein the vector comprises a vector suitable for introduction into a cell *in vivo*.

31. (Original) The composition of claim 30, wherein the vector comprises an adeno associated virus (AAV), adenovirus, retrovirus, parvovirus, papilloma virus, reovirus, rotavirus or a herpes virus.

32. (Original) The composition of claim 30, wherein the vector comprises a plasmid vector.

33. (Canceled)

34. (Previously presented) A kit comprising a composition of claim 1.

35. (Original) A kit comprising a composition of claim 1 further including instructions for expressing the modified blood clotting factor *in vitro, ex vivo or in vivo*.

36.-40. (Canceled)

41. (Previously presented) The composition of claim 1, further comprising a pharmaceutically acceptable carrier.

42.- 63. (Canceled)

64. (Currently amended) A composition comprising a recombinant polynucleotide that encodes a modified Factor IX, ~~wherein the said modified Factor IX comprising modification comprises a proteolytic cleavage site at a location that allows secretion of active Factor IX upon cleavage, said proteolytic cleavage site comprising the amino acid sequence of having the sequence Arg Lys Arg Arg Lys Arg (SEQ ID NO:1), wherein said proteolytic cleavage site is not normally present in Factor IX, and wherein said modified Factor IX is cleaved at the cleavage site when expressed in an animal cell and secreted in an active form.~~

65. (Previously presented) The composition of claim 64, wherein the Factor IX is a functional variant or a functional subsequence of a naturally occurring Factor IX.

66. (Canceled)

67. (Canceled)

68. (Currently amended) The composition of claim 65, wherein the functional variant has one or more conservative amino acid substitutions relative to ~~of~~ wild type Factor IX.

69. (Previously presented) The composition of claim 64, wherein the Factor IX is mammalian.

70. (Previously presented) The composition of claim 69, wherein the Factor IX is primate, canine, feline, porcine, equine or bovine.

71. (Previously presented) The composition of claim 70, wherein the primate is human.

72. (Previously presented) The composition of claim 64, wherein the recombinant polynucleotide encoding the modified Factor IX is operatively linked to a regulatable or tissue specific expression control element.

73. (Previously presented) The composition of claim 72, wherein the regulatable or tissue specific expression control element comprises a promoter.

74. (Currently amended) The composition of claim 72, wherein the promoter comprises a skeletal muscle actin promoter or a muscle creatine~~creatine~~ kinase promoter.

75. (Previously presented) The composition of claim 72, wherein the tissue specific expression control element confers expression of the modified blood clotting factor in muscle, liver, kidney or blood vessel endothelium.

76. (Currently amended) The composition of claim 72, wherein the regulatable expression control element comprises elongation factor la α promoter.

77. (Currently amended) The composition of claim 64, further comprising a vector. A composition comprising a vector comprising a recombinant polynucleotide that encodes a modified Factor IX, said modified Factor IX comprising a proteolytic cleavage site at a location that allows secretion of active Factor IX upon cleavage, said proteolytic cleavage site comprising the amino acid sequence of SEQ ID NO: 1, wherein said proteolytic cleavage site is not normally present in Factor IX.

78. (Previously presented) The composition of claim 77, wherein the vector comprises a vector suitable for introduction into a cell *in vivo*.

79. (Previously presented) The composition of claim 78, wherein the vector comprises an adeno associated virus (AAV), adenovirus, retrovirus, parvovirus, papilloma virus, reovirus, rotavirus or a herpes virus.

80. (Previously presented) The composition of claim 77, wherein the vector comprises a plasmid vector.

81. (Canceled)

82. (Currently amended) A kit comprising the a-composition of claim 64 and instructions for use or a polypeptide of claim 81.

83. (Currently amended) A kit comprising the a-composition of claim 64 further including instructions for expressing the modified Factor IX~~blood clotting factor~~ *in vitro, ex vivo or in vivo.*

84. (Currently amended) The composition of claim~~claims~~ 64, further comprising a pharmaceutically acceptable carrier.

85. (New) A composition comprising a recombinant polynucleotide that encodes a modified Factor VII, said modified Factor VII comprising a proteolytic cleavage site, said proteolytic cleavage site comprising a PACE/furin proteolytic cleavage recognition site at a location that allows secretion of active Factor VII upon cleavage, wherein said proteolytic cleavage site is not normally present in Factor VII.

86. (New) A composition comprising a recombinant polynucleotide that encodes a modified Factor IX, said modified Factor IX comprising a proteolytic cleavage site at a location that allows secretion of active Factor IX upon cleavage, said proteolytic cleavage site comprising a PACE/furin proteolytic cleavage recognition site, wherein said proteolytic cleavage site is not normally present in Factor IX.